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TRANSMITTAL OF NEW PROVISIONAL APPLICATION VIA EXPRESS MAIL NO.: EV399247898US

Box Provisional Patent Application
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LAW
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Re: New U.S. Provisional Patent Application for "DISPOSABLE FLUID SAMPLE COLLECTION DEVICE"; Filed: (Herewith) November 5, 2003; Inventors: Chris Dykes et al; Serial No. to be Assigned

Dear Sir:

Transmitted herewith for filing is the above-referenced provisional patent application. Enclosed are:

1. New provisional patent application; 33 pages total of specification including 11 pages of drawings.
2. Eight(8) Verified Statements to establish small entity status - 37 CFR 1.9 and 37 CFR 1.27 (Ind. Inventor).
3. One(1) Verified Statement (Declaration) Claiming Small Entity Status (37 CFR 1.27 (a) and 1.27 (c)(1))- Small Business Concern
4. Our check No. 3708 in the amount of $80.00 (small entity) to cover filing.
5. Our post card. Please date stamp and return.

Please charge any unanticipated fees to our Deposit Account No. 03-3565 (a duplicate copy of this charge authorization is attached.)

Date

11/05/2003

Respectfully submitted,

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I HEREBY CERTIFY that on November 5, 2003, one copy of the above-referenced documents were deposited with the United States Postal Service for delivery by Express Mail to the United States Patent and Trademark Office.

UNITED STATES PROVISIONAL PATENT APPLICATION

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Invention: **DISPOSABLE FLUID SAMPLE COLLECTION DEVICE**

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DISPOSABLE FLUID SAMPLE COLLECTION DEVICE

BACKGROUND OF THE INVENTION

FIELD OF THE INVENTION.

The invention relates to a method and apparatus for on-the-spot sampling of small amounts of fluid for analysis. More particularly, it relates to a disposable device which operates by a combination of capillary action to collect a small fluid sample (such as blood), and by pressure differential when inserted into an analyzer to move the fluid into and out of a test chamber, exposing the fluid sample for testing by the analyzer.

DISCUSSION OF THE BACKGROUND

Physicians routinely test blood parameters as part of the diagnostic process. The complete blood count (CBC) is the most common of these tests. Physicians use the results to assess the quantity and the condition of the blood's cellular components. Three of the elements of the complete blood count are used to describe the size and number of red blood cells in the sample: the hematocrit (HCT), the mean corpuscular volume (MCV), and the red blood cell count (RBC). Four more blood properties describe the oxygen-carrying capacity of the red blood cells: the hemoglobin concentration (HGB), total protein concentration (TPC), the mean cellular hemoglobin (MCH), and the mean cellular hemoglobin concentration (MCHC).

These blood properties, in particular HCT or HGB, can be used to diagnose anemia, acute blood loss, dehydration, and scores of other conditions. HCT or HGB can also be used to assess the oxygen carrying capability of the blood.

In the hospital environment, medical personnel typically collect blood samples and then transfer the sample to a central blood lab for analysis. Two well-known methods of collecting blood samples include: (1) collecting the sample into a capillary tube following a finger, heel, or earlobe stick, and (2) collecting the blood sample into a vial using a syringe. Capillary tubes are made of glass or hydrophilic plastic open at both ends. One end of the tube is placed against the site of a small incision on the finger, heel, or ear lobe, and blood flows into the tube from the incision by capillary action. In either case the capillary tube or vial containing the blood sample is delivered to the lab where an automated system performs the testing.

Recently, research and development in the area blood collection and testing has been conducted in light of: (1) the risks associated with transfer of blood between containers including contamination of the blood sample and the increased risk to medical or laboratory personnel of exposure to blood-borne communicable diseases, such as hepatitis B, hepatitis C, and HIV; and, (2) the need and desire for accurate on-the-spot analysis of blood samples in emergency situations, blood banks, or in office or home environments. As a result, a variety of portable blood analyzers have been developed which are capable of taking optical, electrical conductivity or ultrasonic readings of a blood sample in order to measure blood components and characteristics such as hematocrit, hemoglobin, mean corpuscular volume, red blood cell count, mean cellular hemoglobin, mean cellular hemoglobin concentration, and total protein concentration. These portable blood analyzers have in turn engendered a need for a single-use disposable device which serves as a collection receptacle, temporary storage container, and testing chamber for blood samples to be used in conjunction therewith.

The general concept of a disposable blood sample collector, which uses capillary action to draw blood from the site of a finger stick or the like, and then transfers the blood to another container or chamber within the same device for centrifuging, is known. The following prior art references illustrate this concept. U.S. Patent No. 4,314,570 to Sarstedt discloses a disposable blood sample collector and storage receptacle having a short capillary tube communicating with a somewhat larger chamber. The chamber is filled, the capillary tube is disconnected, and the chamber containing the blood sample is placed in a centrifuge or tested directly. U.S. Patent 5,472,671 to Nilsson et al. discloses a two cavity blood sample collection device. A blood sample is collected into the first cavity by capillary action and may be mixed with a reagent. The blood sample is then transferred by centrifugal force through a channel into a second cavity. Different reactions/analyses can be carried out in the different cavities. U.S. Patent No. 5,916,814 to Kenney discloses a pre-sealed integral hematocrit test assembly. The assembly essentially comprises a holder for holding together both a blood sample tube and hematocrit test tube during centrifugation, whereby the blood from the sample tube is funneled into the test tube and separated into columns.

Additional devices, which are designed for both collection and testing (other than centrifuging) of blood, are also known. For example, typical home-use blood glucose monitors involve the user inserting a test strip into a monitor, lancing their finger, squeezing out a drop of blood, aiming the drop of blood so that it lands on the small test surface of the test strip. U.S. Patent Application 2003/0007893 of Purcell discloses a testing device for on-the-spot blood glucose monitoring (i.e. by photometric, colorimetric or electrochemical analyzers) that attempts to ensure that the user collects the necessary volume of blood with minimal air bubbles. Purcell developed an elongated test sensor insertable into a monitor. The sensor has a higher volume pick-up area at one end and a lower volume read area at the

other. The read area end is inserted into the monitor. A blood sample from a finger stick is dripped onto and collected in the pick-up area of the test sensor. If the pick-up area volume is filled, an amount of blood required for testing will necessarily flow by capillary action through a transfer area and into a read area containing a reagent, where the monitoring unit reads the results. A cover over the transfer and read areas protects the monitoring unit.

Lastly, the concept of transferring a fluid sample from a collection area to a testing area within a device using a pressure differential is known. U.S. Patent Application 2003/0118479 of Quirk et al. discloses a device that is attached and sealed to a removable test strip (coated with a reagent) forming a testing chamber into which a collected blood sample can be directed towards or away from by inducing a pressure differential on the sample. None of the above devices provide an all-in-one disposable device that collects and temporarily *safely* stores a blood sample for analysis, and which is insertable into the testing region of an analyzer to thereby seal the testing surfaces, forming a sealed testing chamber, and which incorporates or interfaces with an actuator which initiates a pressure differential to move the blood sample into and out of the testing chamber. The unique structure of this device used in conjunction with an analyzer provides a quick, clean and safe way of collecting and testing a predefined amount of blood (or other fluid), especially in emergency or non-laboratory settings.

SUMMARY OF THE INVENTION

Accordingly, one object of the present invention is to provide methods and devices for collecting a fluid sample of a predetermined amount for analysis.

It is another object of the present invention to provide methods and devices for temporarily storing the collected fluid sample.

It is another object of the present invention to provide methods and devices specifically adapted for collecting and storing blood samples and for analyzing the samples therein safely and efficiently.

It is another object of the present invention to provide a disposable blood sampling device that automatically collects a blood sample in a collecting region, and which automatically shifts the blood sample to a testing region.

It is another object of the present invention to collect a blood sample in a collecting region made of hydrophilic plastic tubing which inducts the blood by capillary action.

It is another object of the present invention that the capillary tube is of a predetermined length and diameter to ensure that slightly more than the necessary amount of blood is collected.

It is another object of the present invention that the capillary tube is clear or translucent and is visibly marked with lines to indicate to the user that the necessary amount of blood has been collected.

It is another object of the present invention to provide methods and devices suitable for a blood draw of less than 1 ml, and preferably using a drop of capillary blood as opposed to venous blood.

It is another object of the present invention to provide a disposable blood sampling device suitable for interfacing with a battery-operated, portable, hand-held blood analyzer.

It is another object of the present invention to provide a disposable blood sampling device that is insertable into a portable blood analyzer such that the testing region of the blood sampling device seals with testing surfaces of the blood analyzer to form a hermetically-sealed testing chamber.

It is a further object of the present invention that the testing chamber be in the shape of a cylinder with a square horizontal cross-section to minimize bubble formation.

It is another object of the present invention to provide a disposable blood sampling device with an integral pressure-differential actuator that is activated once the device is inserted into analyzer to cause blood to flow between the capillary collection tube and the testing chamber.

It is another object of the present invention to provide a disposable blood-sampling device that is activated once the device is inserted into analyzer by a pressure differential created by the analyzer, which causes blood to flow between the capillary collection tube and the testing chamber.

It is another object of the present invention to provide a disposable blood sampling device adapted for insertion into an analyzer to measure blood components and characteristics such as hematocrit (HCT), hemoglobin concentrations (HGB), mean corpuscular volume (MCV), red blood cell count (RBC), mean cellular hemoglobin (MCH), mean cellular hemoglobin concentration (MCHC), or total protein concentration (TPC).

BRIEF DESCRIPTION OF THE FIGURES

A more complete appreciation of the invention and many of the attendant advantages thereof will be readily obtained as the same becomes better understood by reference to the following detailed description when considered in connection with the accompanying drawings, wherein:

FIG. 1 is a photograph of the preferred embodiment of the disposable device 100 next to an exemplary portable blood analyzer 200.

FIG. 2 is a drawing illustrating the outer structure of the exemplary portable blood analyzer 200 of FIG. 1 showing an insertion port 201 for receiving the disposable device 100 for testing.

FIG. 3 is a drawing illustrating the front of disposable device 100 according to the preferred embodiment of the invention.

FIG.s 4a and 4b are perspective views of the side of disposable device 100 according to the preferred embodiment of the invention.

FIG. 5 is a detailed drawing of the present invention, including an exploded view illustrating the connection between the collection region and the testing region of the disposable device 100.

FIG.s 6 – 14 and FIG.s 17(a-c) – 19 are drawings illustrating various other embodiments of the invention.

FIG. 15 is an operational sequence diagram of the preferred embodiment of the disposable device 100 as used in conjunction with portable blood analyzer 200.

FIG. 16 is a drawing illustrating the operation of the portable blood analyzer 200 after insertion of the present disposable collection and testing device.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention device is a fluid sampling device which operates by a combination of capillary action to collect a small fluid sample, and by pressure differential when inserted into an analyzer to transport the fluid to a testing region, exposing the fluid sample for testing by the analyzer. The device is herein described in the context of a disposable for blood sampling that is designed to interface with a blood analyzer 200 as shown in Figure 1. One skilled in the art will understand that the concept of the invention

may be employed for sampling and testing virtually any fluid. The sampling device 100 is suitable for collecting .05mL or less (1 drop) of blood, and is adapted for insertion into the analyzer 200 for testing by optical measurement, electrical conductivity measurement, ultrasonic testing, or any other established means. The preferred embodiment of the present invention 100 (as shown in FIG. 1) is shown with the ULTRACRIT™ ultrasonic high accuracy blood analyzer 200 by Key Technologies, Inc., which includes an insertion port 201 for insertion of the sampling device 100.

FIG. 2 illustrates the contoured structure of the insertion port 201 in blood analyzer 200 which is keyed for slidable insertion of the disposable device 100 for testing.

FIGs. 3 and 4 are drawings illustrating front and side views, respectively, of a disposable sampling device 100 according to the presently preferred embodiment of the invention. The sampling device 100 generally comprises an elongate thin plastic supporting frame 7 including a top and bottom (1 and 2), front and back (3 and 4), two sides (5 and 6), with various functional features discussed below. The front 3 and back 4 surfaces are essentially symmetrical, as are the sides (5 and 6). The supporting frame 7 is further comprised of three primary functional regions, a collecting region 10, a testing region 20, and an actuation region 30.

The collecting region 10 comprises an entrance aperture 12 defining the entrance to a collecting receptacle 11 which in the preferred embodiment is a hollow hydrophilic capillary tube with a volume of approximately 50 micro-liters (this is suited for collecting approximately 1-2 drops of blood). However, depending on the particular analyzer for which the device is designed, the volume of the collecting receptacle (capillary tube) 11 may vary from between .01-1 ml. The presently preferred dimensions for the capillary tube are an ID of 2mm and a length of 15mm, although many dimensions are acceptable. The length and ID can be increased to collect a larger sample, or they can be decreased in order to wick quickly and ensure that the receptacle

holds the sample securely. This capillary tube 11 has two opposing ends 12 and 13, end 12 defining an aperture through which blood enters the capillary tube. The other end 13 is in fluid connection with a testing region 20 (see below). The capillary tube is relatively clear or translucent and preferably includes a visible indicator line or graduated markings to indicate to the user that enough blood has been acquired. In practice, a patient's blood will be drawn by a pin prick (as described below), the capillary tube 11 of sampling device 100 will be placed in contact with the blood, and the blood will be inducted by capillary action into the tube 11 until a sufficient quantity is collected. Once done, the capillary tube 11 also serves as the temporary storage receptacle for the blood during transit from the patient to the analyzer 200.

The testing region, as best seen in FIG. 5, is an open window formed by a transverse aperture 21 through the front 3 and back 4 surfaces of the supporting frame of the sampling device 100. Preferably, the aperture 21 is cylindrical to define a round-walled testing region with square or rectangular cross section. The cylindrical shape (a round aperture with flat sides) deters air bubbles from forming in the testing region, while also minimizing the amount of blood required for accurate testing. The rims surrounding the aperture 21 on both the front 3 and back 4 surfaces of the device are preferably equipped with sealing rings 22, made of a material such as flexible rubber or plastic. The sealing rings 22 may be a single grommet inserted through the testing region, or alternatively may be individually attached or integrally molded thereto. This way, when the sampling device 100 is inserted into the analyzer 200, the walls of the insertion slot 201 of analyzer 200 mate with the sealing rings 22 to hermetically seal the aperture 21, and a closed cylindrical testing chamber 26 is formed (See Figures 15 and 16). Depending on the particular analyzer for which the device is designed, the volume of the sealed testing chamber may range from .01 to 1 ml. The passage of the capillary tube 11 traverses the testing channel 25 at two holes (23 and 24) located opposite each other. Thus, if the sealing rings 22 are

implemented by a single grommet through the testing region the grommet must likewise incorporate holes in alignment with holes 23 and 24.

The passage of the capillary tube 11 is in fluid communication with an actuator region 30, which includes a hollow actuator tube 31 leading into an actuator bulb 32. The actuator tube 31, including ends 34 and 35, is integrally molded (or attached and sealed) at end 34 to the edges of hole 24 of testing channel 25. The actuator bulb 32 is preferably made of flexible rubber or plastic and is integrally molded in the front 3 and back 4 surfaces of the sampling device 200. The actuator bulb 32 is sealed such that air may only escape through actuator tube 31, and this may be accomplished by molding and welding two half-sections or by unitary molding of the device 100.

Additional structural features include, the sides 5 and 6 of the supporting structure having symmetrical notches 33. These notches 33 are located such that when the device 100 interfaces with the analyzer 200, the testing region 20 of device 100 is aligned concentric with the sensors 227 of the analyzer 200 (See FIG. 15). The front 3 and back 4 surfaces of the supporting structure approximate to the top end 1 includes textured finger grips 37 (i.e. ridges or bumps) to help prevent dropping of the device during blood collection and transfer to the analyzer.

While the preferred embodiment of the invention is made generally of hard plastic with the sealing rings 22 and the actuator bulb 32 being made of flexible rubber or soft plastic, the entire invention may be formed from a flexible rubber or hard plastic material. Other possible materials include glass, polystyrene, polyamide, polyvinylchloride, polycarbonate, silicone, polypropylene, polyurethane, latex or polyethylene. The choice of materials and surface finishes for the device are preferably chosen to prolong the onset of coagulation (i.e. polystyrene). This is particularly desirable when using untreated capillary blood in an ultrasonic analyzer because it has been demonstrated that the biochemical process of coagulation changes the speed of sound

over time. Surface finishes are preferably smooth to minimize the surface area, allowing the blood to flow more freely through the device and prolong the onset of coagulation.

If it is anticipated that the time between drawing blood and test completion will be significant (i.e. longer than 2 minutes, thereby causing coagulation which effects the speed of sound through the blood), powdered heparin anticoagulant, EDTA or other anticoagulants, may be coated inside the device to retard coagulation without distorting red blood cells.

The sampling device 100 may be manufactured by shooting both materials (the hard plastic for the supporting frame and the flexible rubber or plastic for the sealing rings 22 and bulb 32) into a two-shot mold. However, one skilled in the art will understand that the device may also be manufactured in a single-shot mold, or may be constructed as separate parts, for example, the flexible material components may be attached to the hard plastic support frame. The various parts may be connected by snaps, adhesive, ultrasonic welding, or any other method of securing differing plastic or rubber materials. The sampling device may also be formed using blow molding.

FIG. 11 illustrates an embodiment in which a flexible testing region 1120 and actuation region 1130 forming one part may be connected by some means (i.e. snaps, adhesive, ultrasonic welding, or any other method of securing differing plastic or rubber materials) to a separate hard supporting frame which includes the entrance region 1110.

OPERATION OF THE DEVICE

FIG. 15 is an operational sequence diagram of the preferred embodiment of the disposable device 100 as used in conjunction with portable blood analyzer 200.

FIG. 16 is a drawing illustrating the operation of the portable blood analyzer 200 after insertion of the present disposable collection and testing device.

As stated above, the preferred embodiment of the sampling device is suitable for docking with any fluid analyzer equipped with an insertion port 201 as shown in FIG. 2, and capable of analyzing the small sample contained in collected in collecting region 10. The Ultracrit ™ ultrasonic blood analyzer by Key Technologies as shown in Figure 1 is but one example.

In use, a blood sample is obtained by lancing the skin (i.e. by finger, heel or ear lobe stick) to obtain a capillary blood sample. The end 12 of capillary tube 11 is placed immediately adjacent to the incision site and the blood is drawn into capillary tube 11 by capillary action. When the user sees through the clear or translucent capillary tube 11 that enough blood has entered the tube (e.g., blood has reached indicator line 15), the device is moved away from the incision site. Capillary tube 11 serves as the temporary storage receptacle, until the device 100 can be inserted into analyzer 200 for analysis. Reducing the time between blood draw and completion of the analysis to less than 2 minutes reduces the influence of coagulation on the speed of sound traveling through blood and, thus, the results of ultrasonic blood analysis.

The frame structure of the device 100 is specifically designed to mate with port 201 of the analyzer 200 (See Figures 1 and 2), and the port 201 requires certain structure to activate the device 100. Figure 15 is an operational schematic drawing illustrating the interface between the device 100 and analyzer 200. As illustrated, the device 100 is inserted into port 201 with blood sample already in the capillary tube 11. The port 201 is formed with constricted sides (or protrusions) 210 at a predetermined depth. Thus, as device 100 is inserted, the sides of the port 201 depress the actuator bulb 32 forcing air through actuator tube 31 into testing cylinder 25 and out apertures 21. As device 100 continues into port 201, the actuator bulb 32 remains depressed and the sealing rings 22 act as a wiping mechanism, cleaning the parallel sensing surfaces 228 (which may include one or more sensors 227) within the analyzer 200. Notches 33 (See FIG. 3) on device 100 indicate how far the device should be inserted such that the testing region 30 of

the device aligns concentrically with the sensor 227 of the analyzer 200. When inserted correctly, the sealing rings 22 will form a hermetic seal against the sensing surfaces 228, thereby forming a closed testing chamber 26.

Analyzer 200 comprises a mechanism for releasing one or both of the sides 210 of port 201 that depressed actuator bulb 32 (this may be accomplished by a solenoid or simply by the sampling device 100 being inserted past the constricted sides (or protrusions) at a predetermined depth in port 201, such that the actuator bulb 32 is no longer depressed. This creates a vacuum which draws the blood stored in capillary tube 11 into the testing chamber 26. In the preferred embodiment (See FIG. 16) this testing chamber 26 allows the blood to directly contact the parallel sensing surfaces 228 of the ultrasonic sensor 227 to optimize the measurement (ultrasonic or otherwise) by improving accuracy of the measurement, and of temperature control. Once the analysis is complete, the sampling device 100 is withdrawn, the sides of the port 21 are again positioned to depress the actuator bulb, thus using air pressure to force the blood out of the testing chamber 26 and back into capillary tube 11. As the device 100 is removed from the analyzer 200, the sealing rings 22 again serve as a wiping mechanism, cleaning off the sensing surfaces 228. The danger of inadvertent exposure to the blood is eliminated by the sequential use of capillary action and pressure-differential to move the blood from containment, to sample chamber, and back, automatically upon insertion and withdrawal.

ADDITIONAL EMBODIMENTS

Figures 3 through 5 illustrate that in the preferred embodiment of the invention in the collection region 10, the testing region 20 and the actuation region 30, respectively, are oriented vertically from the bottom 2 to the top 1 of the supporting frame 7 of the device. However, this orientation is not a functional requirement. The orientation of the functional regions of the

device (i.e. the collection region 10, the testing region 20 and the actuation region 30) is a function of the structure of particular analyzer with which the device will interface. FIG. 6 illustrates an embodiment in which the testing region 620 and the actuation region 630 are side-by-side above the collection region 610. FIG. 7 illustrates an embodiment in which the functional regions are oriented vertically with the collection region 710 at the bottom, the actuation region 730 in the middle and the testing region 720 at the top. FIG. 8 illustrates an embodiment in which the device is designed to be inserted horizontally into a side port on an analyzer. In this embodiment the functional regions are also oriented horizontally.

Figures 3 through 5 further illustrate that in the preferred embodiment of the invention the entrance region comprises a capillary tube 11 having an end 12 defines an aperture with a small diameter through which blood enters a flows through the tube by capillary action. Other embodiments would replace the capillary tube with a different collecting mechanism.

Figures 12 and 13 varying collecting regions 1210 and 1310, respectively. FIG. 12 illustrates an embodiment with a rectangular aperture 1212 defining the entrance through which blood flows into the device. If the rectangular aperture is narrow enough (roughly 1mm or less on its shorter dimension), it will hold the sample securely by capillary action, just like the cylindrical capillary tube holds the sample. The blood is then immediately funneled into a narrow tube 1211 which connects to the testing region 1220. FIG. 13 illustrates another embodiment in which the entrance aperture 1312 is rectangular. In this particular embodiment the rectangular aperture 1312 defines the entrance to a rectangular channel 1311 which funnels at the opposite end into the testing region 1320.

Figures 3 through 5 further illustrate that in the preferred embodiment of the invention collecting receptacle 11 is a capillary tube that is a straight relatively short tube leading directly from the bottom end 2 of the supporting frame 7 to the testing region 20. For example, in the

preferred embodiment of the present invention this tube is a capillary tube with an ID of 2mm and a length of 15mm, although many dimensions are acceptable. However, the length and ID can be increased to collect a larger sample, or they can be decreased in order to wick quickly and ensure that the receptacle holds the sample securely.

Other embodiments of the present invention may vary the length or shape of the collection region to increase the surface area over which the blood passes in order to hasten thermal equilibrium between the blood and the device. FIG. 9 illustrates one such embodiment of the invention in which the collecting region 910 includes a capillary tube 911 that is significantly longer than the capillary tube 11 illustrated in Figures 3-5, possibly 100mm long. To accommodate this increase in length, the capillary tube 911 is looped several times before connecting to testing region 920. FIG. 10 illustrates an embodiment in which the collecting region 1010 includes a small aperture 1012 defining the enterance of a capillary tube 1011. The capillary tube then expands forming a wide flat cavity 1017 leading to another capillary tube 1018 which connects to the testing region. The wide top and bottom parallel plates of this flat cavity 1017 provide a large surface area that promotes thermal equilibrium while also deterring the formation of bubbles. Yet another embodiment (not shown) of the invention that is designed to hasten temperature equilibrium includes a piece of metal incorporated into the support frame of the device which would come in direct or close contact with the blood in order to more quickly equilibrate the blood temperature to ambient temperature.

Additional embodiments of the invention are designed with actuation regions that create a pressure differential by a means other that a full sized actuation bulb. FIG. 17, including Figures 17a, 17b, and 17c, illustrates one such embodiment. Specifically, FIG. 17 illustrates a disposable sampling device used in conjunction with analyzer 200 that is equipped with a pump 1799 to replace the actuator bulb This pump 1799, internal to the analyzer 200, creates the necessary

pressure differential to move the blood into the testing region 1720 from collection region 1710. Many means exist for implementing this pump in the analyzer. In the configurations of the disposable device as illustrated in FIG. 17a-c, the actuation region 1730 of the disposable device preferably comprises a seal 1798 on an outer surface of the support structure surrounding an opening 1738 to actuation tube 1731 which is connected to the testing region 1720. Upon insertion into the analyzer 200, the seal 1798 mates with the analyzer 200. Through this seal opening 1738 and actuation tube 1731, the analyzer communicates the pressure differential in order to move the blood from the collection region 1710 into the testing region 1720. The seal 1798 may comprise a single O-ring at the top 1701 of the disposable device (FIG. 17a), a single O-ring on one of the sides 1705 or 1706 of the device (FIG. 17b) or dual symmetric O-rings on the front 1703 and back 1704 faces of the device (FIG. 17c).

Figure 18 illustrates yet another embodiment of the actuator region 1830 of the present invention. Specifically, the actuator region 1830 is formed by a half-bulb 1832 on the front 1803 surface of the device. The back surface 1804 of the device is defined by an aperture 1838 opening onto the inside surface of half-bulb 1832. The back surface 1804 surrounding the edge of the aperture 1838 comprises a seal 1898. Upon insertion of the device into the analyzer 200, the seal 1898 mates with a flat surface of analyzer 200 forming a sealed half-bulb actuator. This embodiment increases the manufacturability of the present invention. Similarly, the embodiment depicted in FIG. 19 employs a half-bulb actuator 1932. An aperture 1938 on the back surface 1904 of the device opens to the inside of the half-bulb 1932. This aperture 1938 is covered by a label 1939 to seal the bulb, increasing the manufacturability of the device.

One method of using the preferred or other embodiments of the present invention to hasten temperature equilibrium includes forcing the blood, by depressing and releasing an

actuator bulb (or by intermittent pump induction), to flow from the collection region to the testing region and back several times before commencing the analysis. This practice mixes the blood, ensuring temperature equilibrium and suspension of the RBC's during testing.

Figures 3 through 13 and 17(a-c) through 19 illustrate that the preferred embodiment of the present invention contains a testing region with a circular shape. This circular shape reflects the circular shape of the ultrasonic measurement beam of the Ultracrit™ ultrasonic analyzer. Having a testing region that mimics the shape of the measurement beam minimizes the amount of blood required for accurate analysis.

FIG. 14 illustrates another possible embodiment in which the testing region 1420 is tear-drop shaped with a round bottom and pointed top. This tear-drop shape encourages any air bubbles to move up into the pointed top area and away from the round bottom area through which the ultrasonic measurement beam emitted by the analyzer travels. Another possible embodiment (not shown) includes additional wipers to clean the surface. These wipers are preferably made of the same flexible material as the sealing-rings and configured as ridges that wipe the surfaces of the sensors as the present invention is inserted into and removed from the analyzer.

As described above, before the device is removed from the analyzer, all blood should be moved out of the testing chamber (which will no longer be sealed) and into a closed chamber. In the preferred embodiment of the present invention, this is accomplished by once again depressing the actuator bulb 32 by some mechanism (i.e. a mechanism within the analyzer that causes the port 201 sides to move back into place against the actuator bulb 32). Depressing the actuator bulb 32 forces air into the testing chamber 26 and causes the blood to flow back into the entrance region 10, where it remains. The entrance region 10 can be capped for disposal. Other embodiments (not shown) would provide a separate holding region into which blood would be

forced (i.e. by pressure differential) after the testing is complete. Another embodiment (not shown) would only partially release the actuator bulb to cause blood flow into the testing region. Once testing is complete the actuator bulb would be fully released causing blood to move up into the actuation region and contained therein. In all embodiments after the device is removed from the analyzer it is thrown away.

Having now fully described this invention, it will be apparent to one of ordinary skill in the art that many changes and modifications can be made thereto without departing from the spirit or scope of the invention as set forth herein.

CLAIMS

We claim:

1. A fluid sample collection and testing device for interfacing with an analyzer, comprising:

a support frame formed with fluidic connections between a collection region, a testing region and an actuator region contained therein, wherein said collection region comprises an entrance aperture through which fluid enters the device by capillary action and flows into said collecting region, and said actuation region creates a pressure differential to force said fluid to flow into said testing region.

2. The device of claim 1, wherein said device is disposable.

3. The device of claim 1, wherein said collecting and temporary storage receptacle of said collection region comprises a capillary tube for collecting a capillary blood sample by capillary action.

4. The device of claim 1, wherein said actuation region comprises an actuator bulb for affecting a pressure differential within the testing region and said analyzer has a mechanism for depressing or releasing said actuator bulb.

5. The device of claim 1, wherein said analyzer is of a type which internally creates a pressure differential; upon interfacing with said device said analyzer communicates

this pressure differential through a port and actuator tube of said actuation region and into said testing region.

ABSTRACT

A fluid sampling device which operates by a combination of capillary action to collect a small fluid sample, and by pressure differential when inserted into an analyzer to expose the fluid sample for testing by the analyzer. The device is especially suited for use as a disposable blood sampling unit that is designed to interface with a blood analyzer, albeit the concept of the invention may be employed for sampling and testing virtually any fluids.

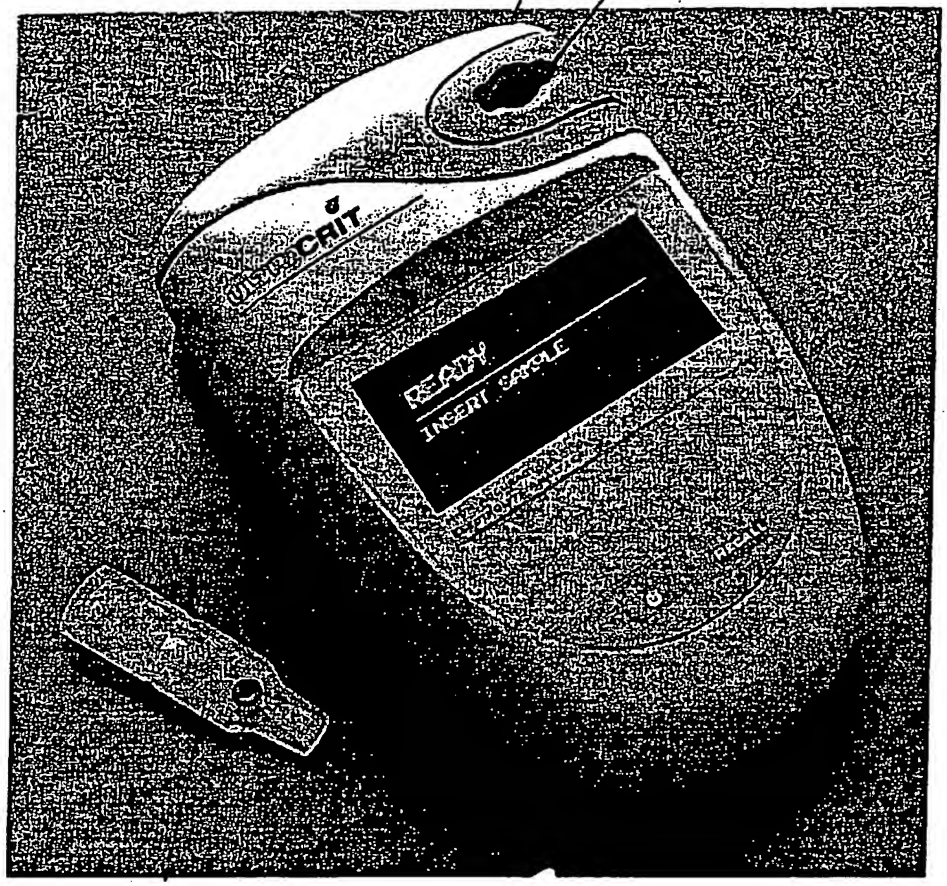


FIG. 1

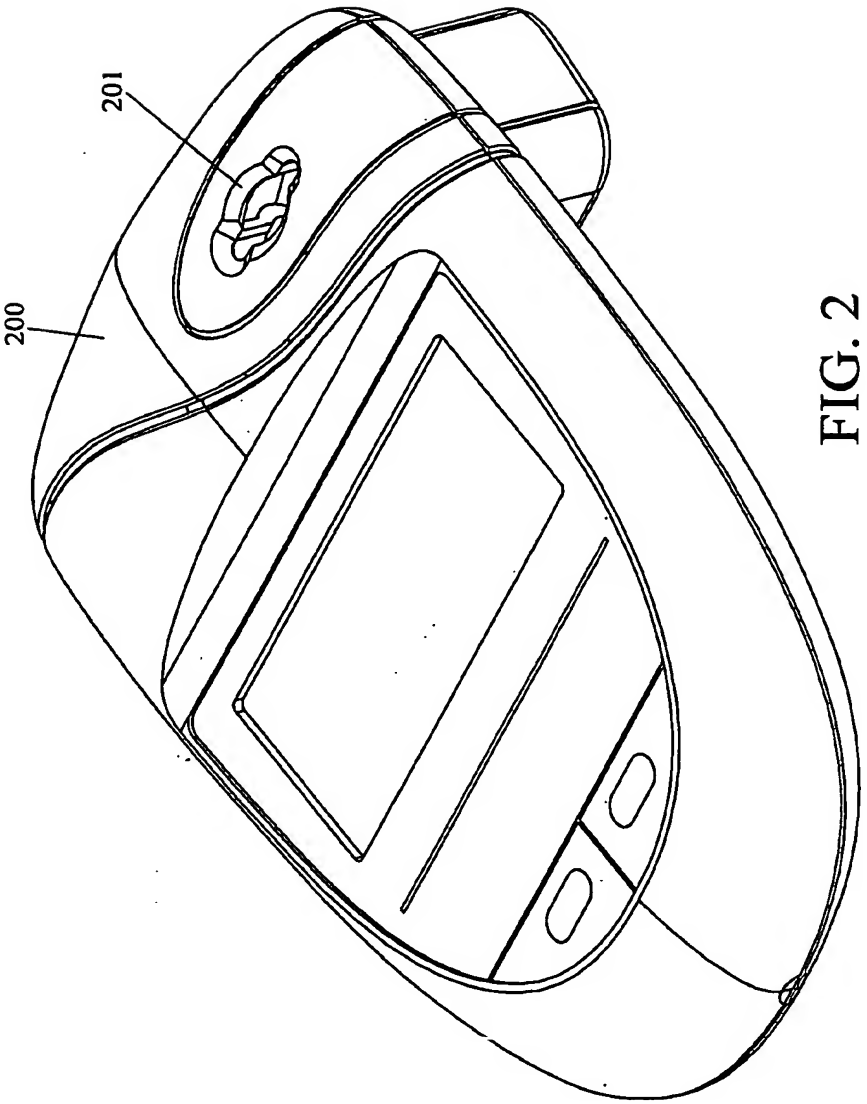


FIG. 2

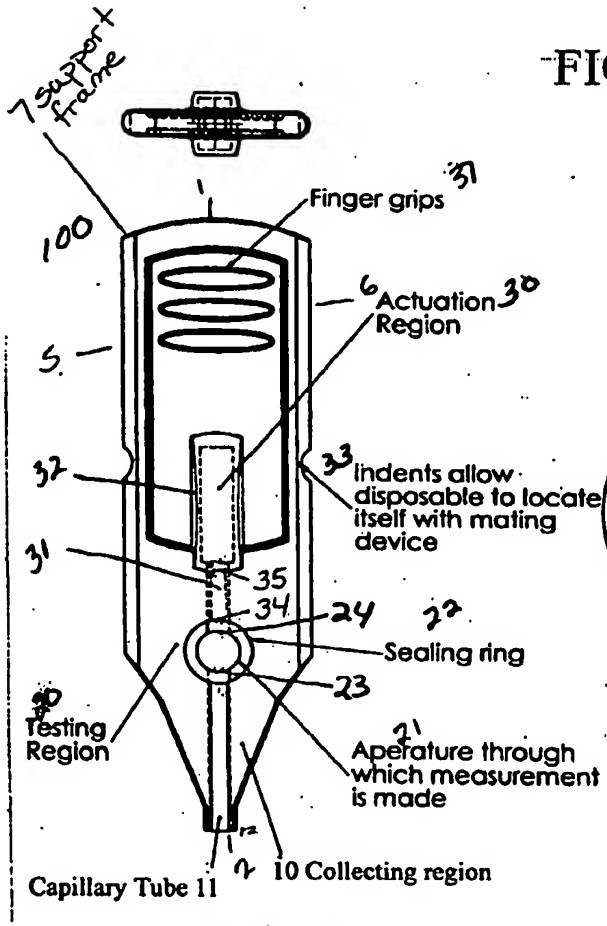


FIG. 3

FIG. 4

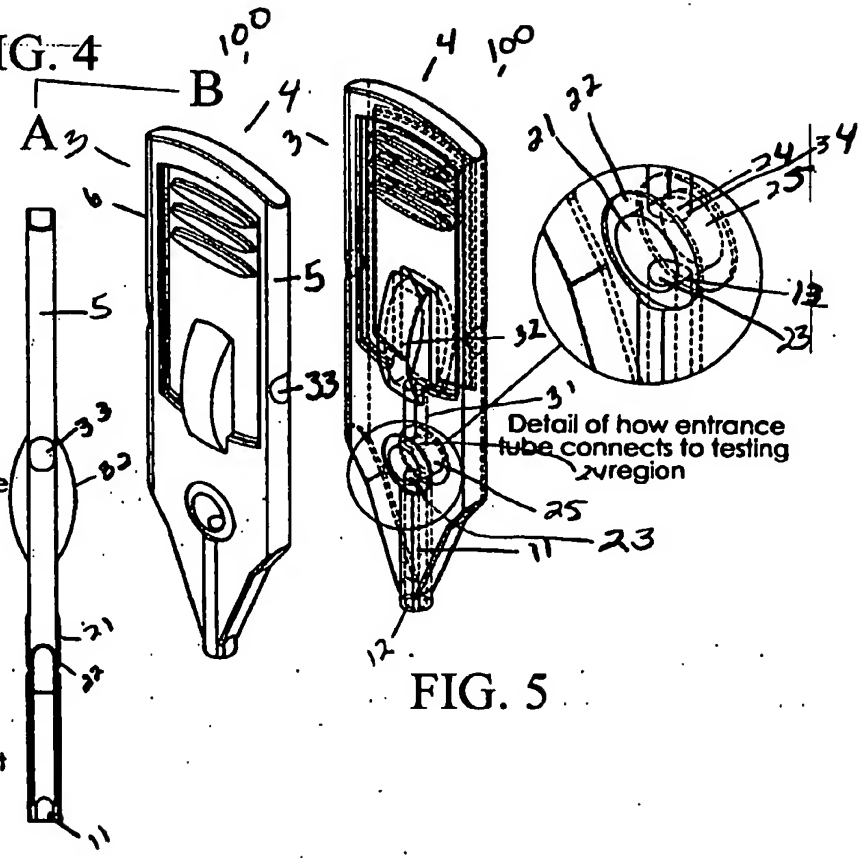


FIG. 5

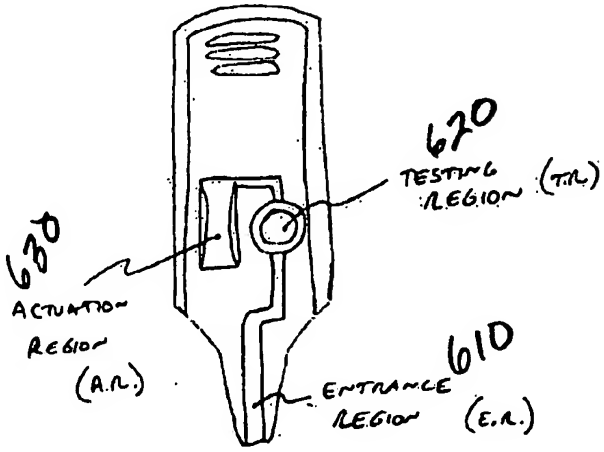


FIG. 6

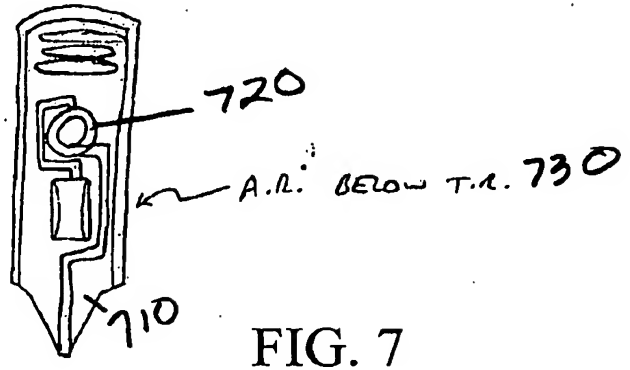


FIG. 7

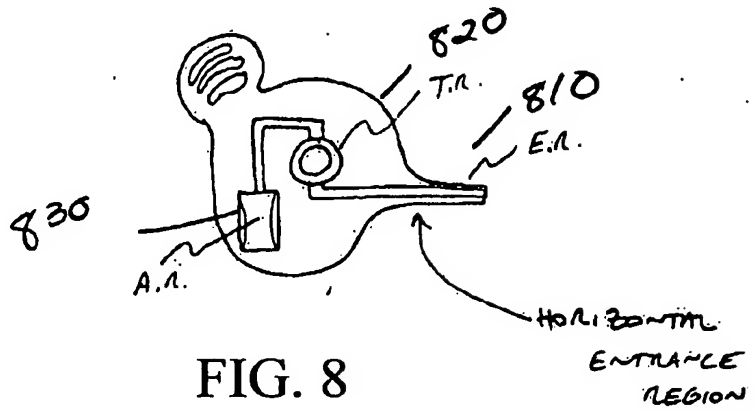


FIG. 8

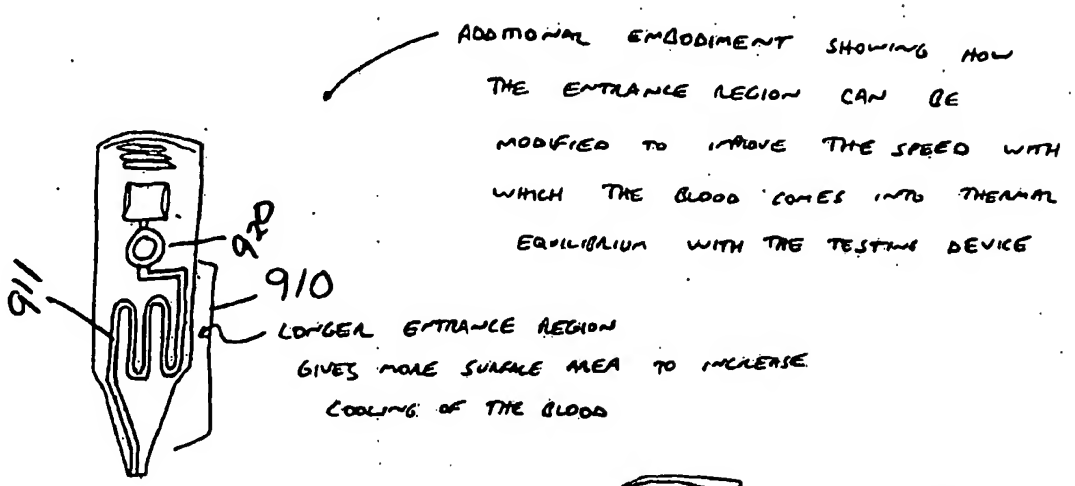


FIG. 9

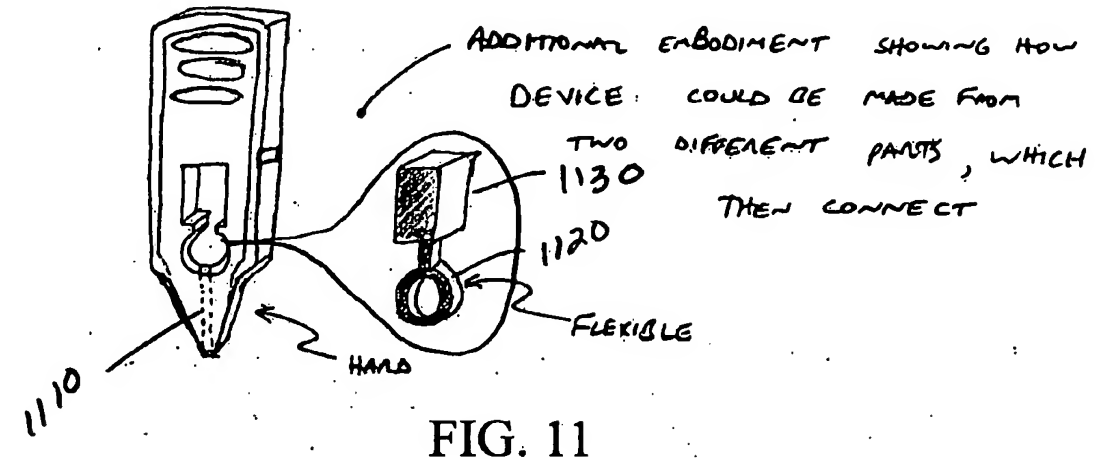


FIG. 11

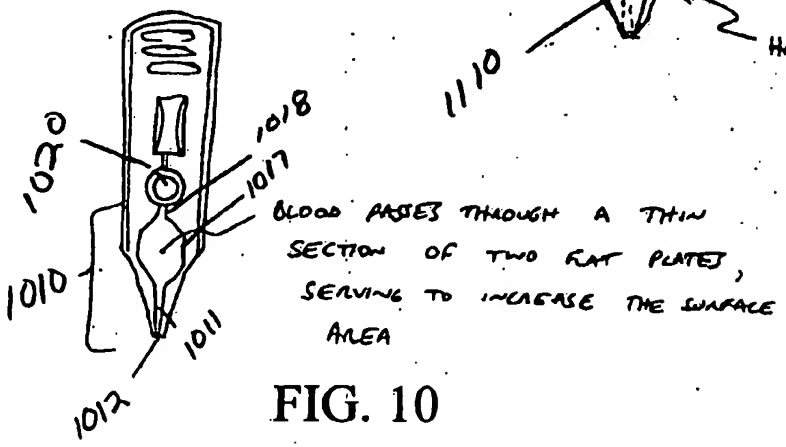
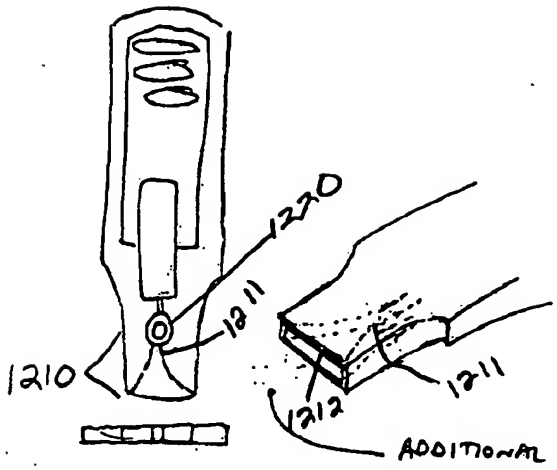


FIG. 10



ADDITIONAL POSSIBLE EMBODIMENT OF ENTRANCE REGION AT TWO PARALLEL PLATES WITH A CHANNEL WHICH NARROWS TO THE TESTING AREA

FIG. 12

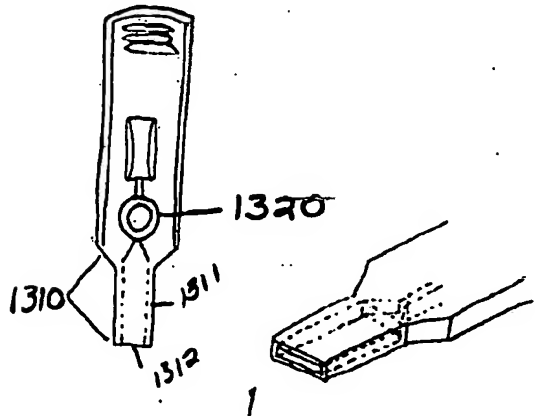


FIG. 13

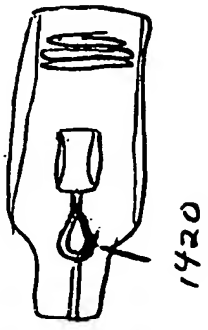


FIG. 14

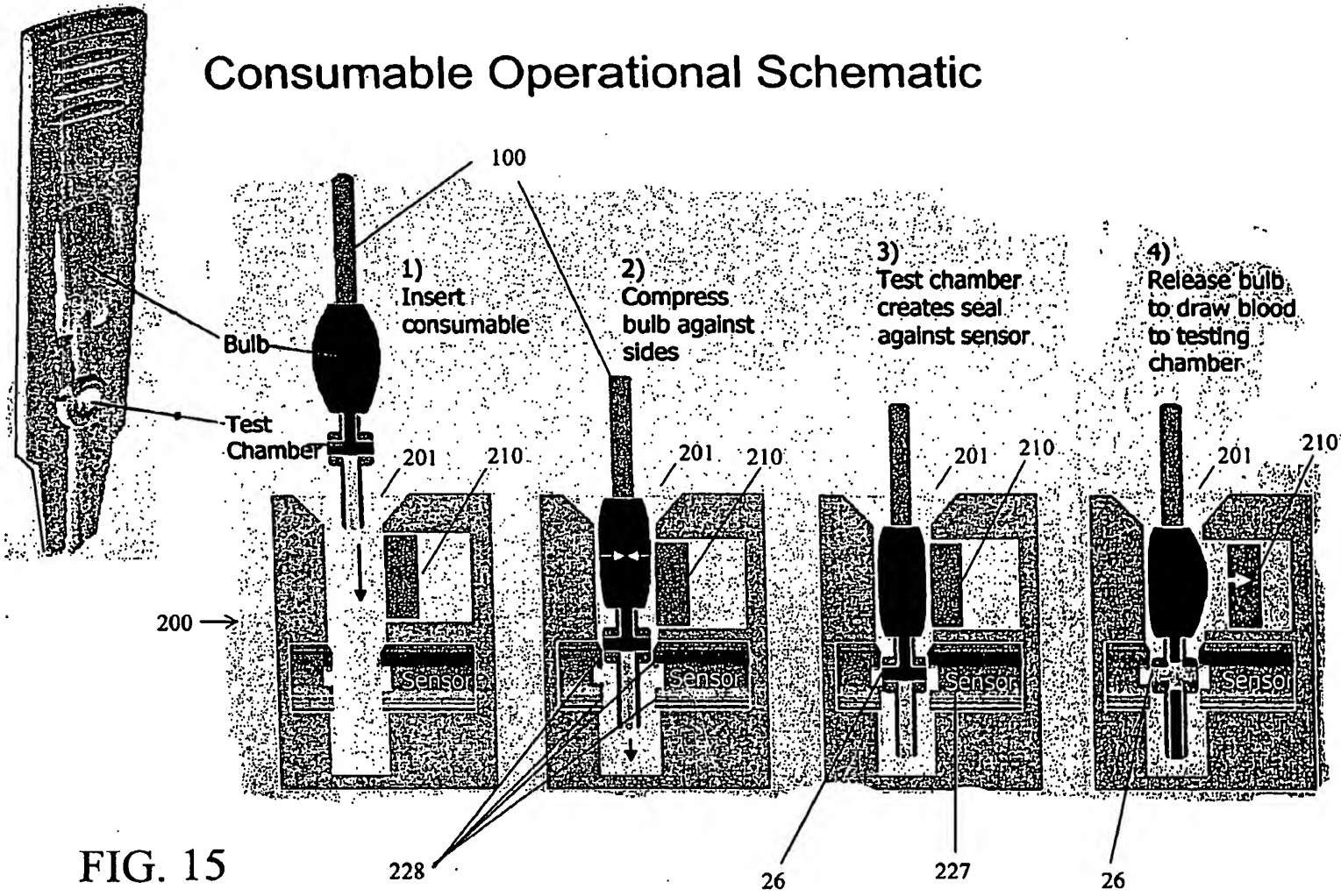

Consumable Operational Schematic
100
Bulb
Test Chamber
1) Insert consumable
2) Compress bulb against sides
3) Test chamber creates seal against sensor
4) Release bulb to draw blood to testing chamber
201
210
200
Sensor
228
26
227
26

FIG. 15

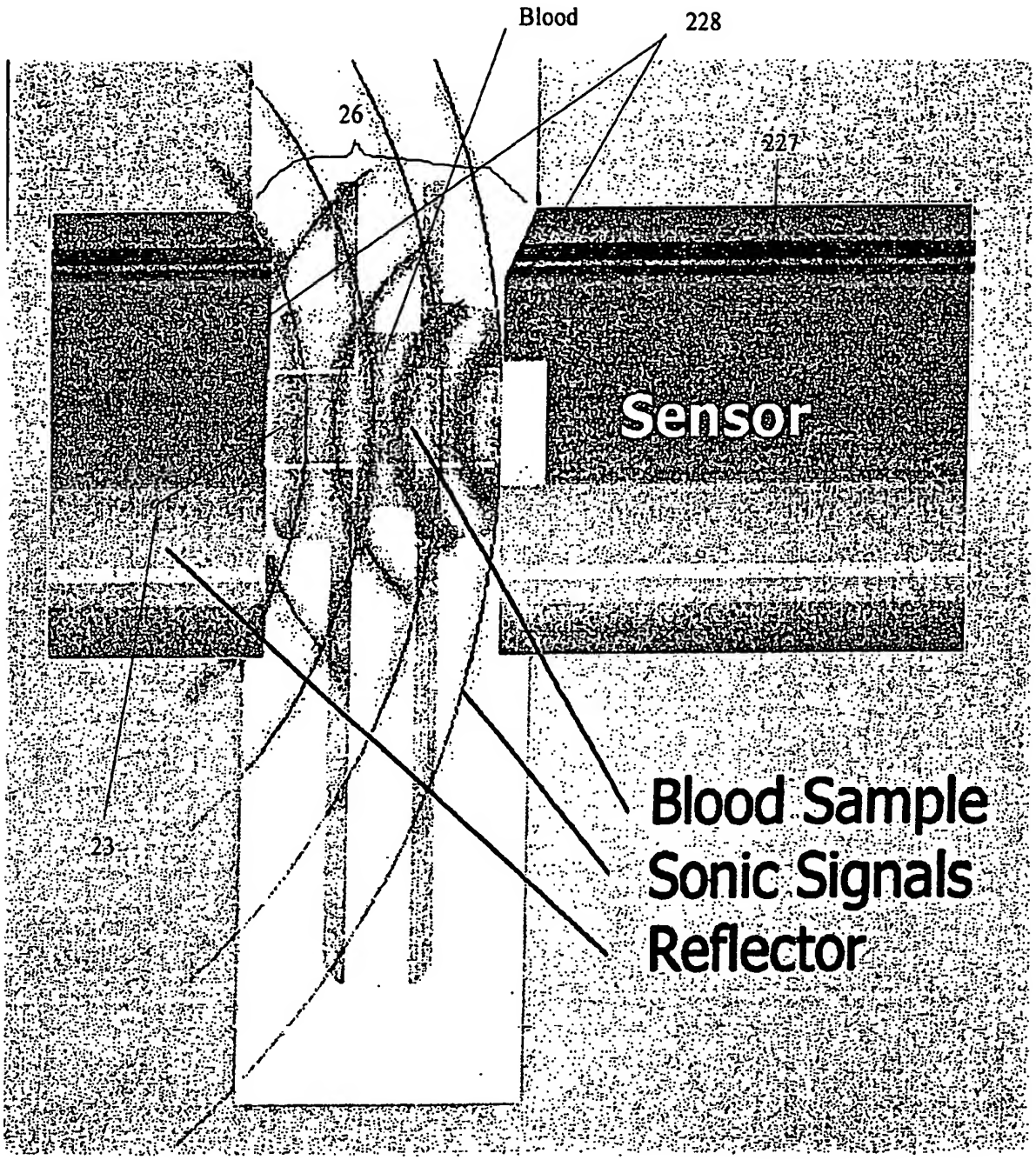

Blood
228
26
227
Sensor
23
Blood Sample
Sonic Signals
Reflector

FIG. 16

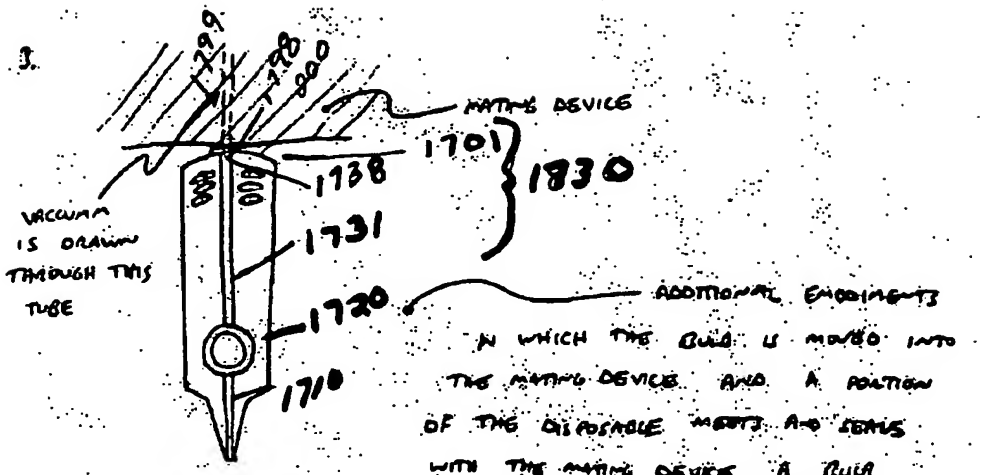


FIG. 17A

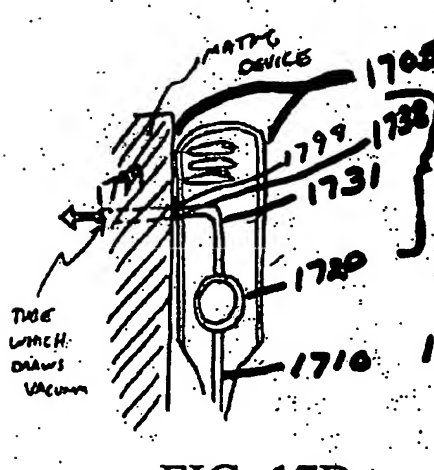


FIG. 17B

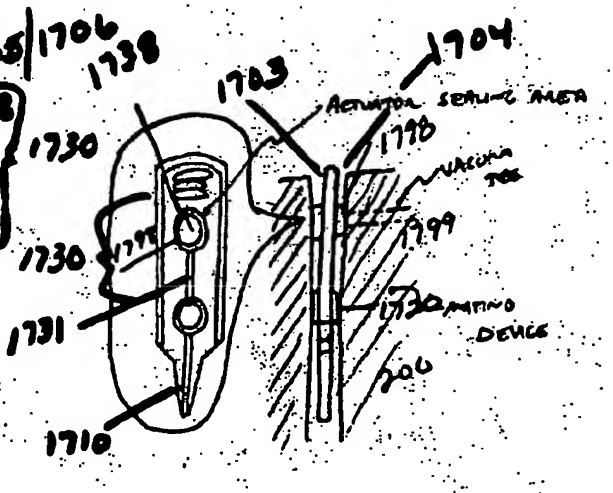


FIG. 17C

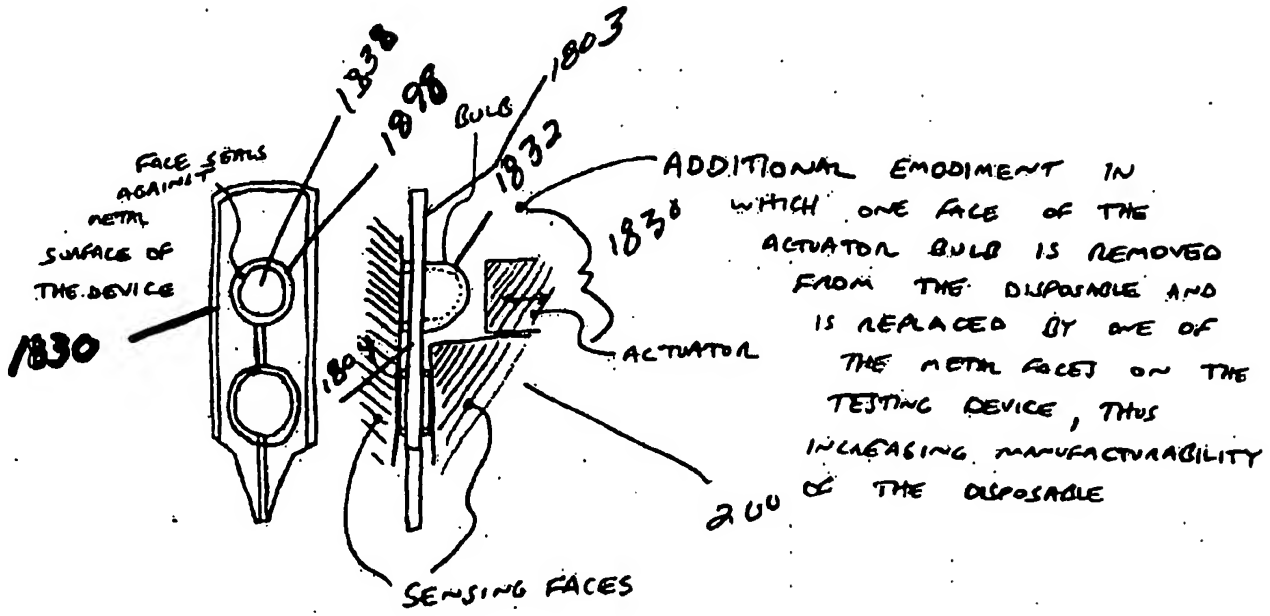
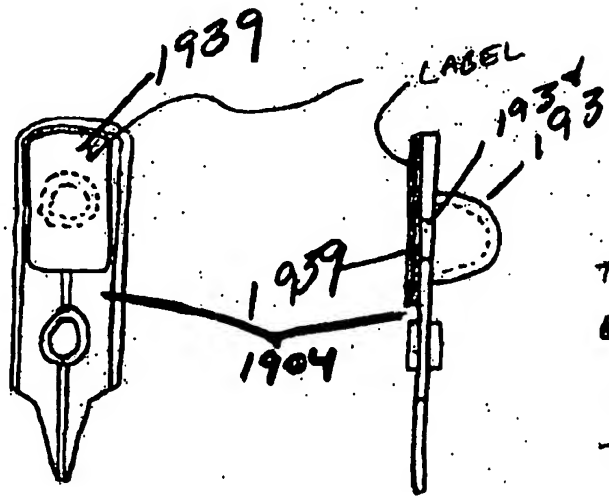

1838
1898
1803
BULB
1832
FACE COMES AGAINST METAL SURFACE OF THE DEVICE
1830
ACTUATOR
2000
SENSING FACES
ADDITIONAL EMODIMENT IN WHICH ONE FACE OF THE ACTUATOR BULB IS REMOVED FROM THE DISPOSABLE AND IS REPLACED BY ONE OF THE METAL FACES ON THE TESTING DEVICE, THUS INCREASING MANUFACTURABILITY OF THE DISPOSABLE

FIG. 18



ADDITIONAL EMBODIMENT IN WHICH ONE FACE OF THE BULB IS REMOVED FROM THE DISPOSABLE AND IS REPLACED BY A LABEL WHICH SEALS THE OTHER SIDE OF THE BULB. THE ACTUATOR THEN PRESSES ON EITHER THE BULB OR THE LABEL SIDE. THIS IS DONE TO INCREASE MANUFACTURABILITY

FIG. 19

Applicant or Patentee: LIPFORD, Brian Attorney's Docket No: KEY Technologies-PPA-5
Serial or Patent No.: To be assigned
Filed or Issued: November 5, 2003
For: DISPOSABLE FLUID SAMPLE COLLECTION DEVICE

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.27(a) and 1.27(c)(1)) - SMALL BUSINESS CONCERN

FULL NAME: KEY TECHNOLOGIES, Inc.
ADDRESS: 40 East Cross Street
Baltimore, Maryland 21230

[ ] INDIVIDUAL [X] SMALL BUSINESS CONCERN [ ] NON PROFIT ORGANIZATION

I hereby declare that the above-identified small business concern qualifies as a small business concern as defined in 37 CFR 1.27(a)(2), for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, in that the number of employees of the concern, including those of its affiliates, does not exceed 500 persons. For purposes of this statement, (1) the number of employees of the business concern is the average over the previous fiscal year of the concern of the persons employed on a full-time, part-time or temporary basis during each of the pay periods of the fiscal year, and (2) concerns are affiliates of each other when either, directly or indirectly, one concern controls or has the power to control the other, or a third party or parties controls or has the power to control both.

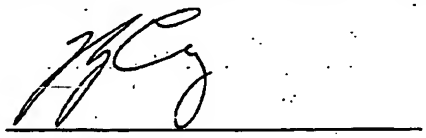
I hereby declare that rights under contract or law have been conveyed and remain with the small business concern identified above with regard to the invention entitled DISPOSABLE FLUID SAMPLE COLLECTION DEVICE described in

[X] the specification filed herewith (November 5, 2003)
[ ] provisional application serial no. _____ [ ] patent no. ____, [ ] issued [ ] filed [ ]

The rights held by the above-identified small business concern are exclusive and no rights to the invention are held by any person, other that the inventor, who could not qualify as a small business concern under 37 CFR 1.27(a)(2) or by any concern which would not qualify as a small business concern under 37 CFR 1.27(a)(2) or a nonprofit organization under 37 CFR 1.27(a)(3).

I acknowledge the duty to file, in this application or patent, new determination of entitlement to small entity status, or notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR §1.27(g)(1)&(2)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made shall be considered as a fraud practiced or attempted on the Office (37 CFR §§1.27(h)(1)&(2)), and are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.



Royal W. Craig
(Attorney for Applicant)

Date November 5, 2003 Reg. No. 34,145

Applicant or Patentee: DYKES, Chris Attorney's Docket No: KEY Technologies-PPA-5
Serial or Patent No.: To be assigned
Filed or Issued: November 5, 2003
For: DISPOSABLE FLUID SAMPLE COLLECTION DEVICE

STATEMENT CLAIMING SMALL ENTITY STATUS
(37 CFR §1.27(a) and 1.27(c)(1)) - INDEPENDENT INVENTOR

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[ ] provisional application serial no. _____, [ ] patent no. _____, [ ] issued [ ] filed

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Royal W. Craig
(Attorney for Applicant)
Reg. No. 34,145

Date November 5, 2003

Applicant or Patentee: LANE, Ben Attorney's Docket No: KEY Technologies-PPA-5
Serial or Patent No.: To be assigned
Filed or Issued: November 5, 2003
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Royal W. Craig
(Attorney for Applicant)
Reg. No. 34,145

Date November 5, 2003

Applicant or Patentee: ABBOTT, Mike Attorney's Docket No: KEY Technologies-PPA-5
Serial or Patent No.: To be assigned
Filed or Issued: November 5, 2003
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Royal W. Craig
(Attorney for Applicant)
Reg. No. 34,145

Date November 5, 2003

Applicant or Patentee: MURPHY, Brian Attorney's Docket No: KEY Technologies-PPA-5
Serial or Patent No.: To be assigned
Filed or Issued: November 5, 2003
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Royal W. Craig
(Attorney for Applicant)
Reg. No. 34,145

Date November 5, 2003

Applicant or Patentee: DIXON, Eva Attorney's Docket No: KEY Technologies-PPA-5
Serial or Patent No.: To be assigned
Filed or Issued: November 5, 2003
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Royal W. Craig
(Attorney for Applicant)
Reg. No. 34,145

Date November 5, 2003

Applicant or Patentee: BEAN, Brian Attorney's Docket No: KEY Technologies-PPA-5
Serial or Patent No.: To be assigned
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Baltimore, Maryland 21230

[ ] INDIVIDUAL [X] SMALL BUSINESS CONCERN [ ] NON PROFIT ORGANIZATION

I acknowledge the duty to file, in this application or patent, new determination of entitlement to small entity status, or notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR §1.27(g)(1)&(2)).

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made shall be considered as a fraud practiced or attempted on the Office (37 CFR §1.27(h)(1)&(2)), and are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

Royal W. Craig
(Attorney for Applicant)
Reg. No. 34,145

Date November 5, 2003

Applicant or Patentee: LIPFORD, Brian Attorney's Docket No: KEY Technologies-PPA-5
Serial or Patent No.: To be assigned
Filed or Issued: November 5, 2003
For: DISPOSABLE FLUID SAMPLE COLLECTION DEVICE

STATEMENT CLAIMING SMALL ENTITY STATUS
(37 CFR §1.27(a) and 1.27(c)(1)) - INDEPENDENT INVENTOR

The below named inventor qualifies as an independent inventor as defined in 37 CFR §1.27(a) for purposes of paying reduced fees under sections 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled DISPOSABLE FLUID SAMPLE COLLECTION DEVICE described in

[X] the specification filed November 5, 2003
[ ] provisional application serial no. _____, [ ] patent no. _____, [ ] issued [ ] filed

The below named inventor has not assigned, granted, conveyed or licensed and is under no obligation under contract or law to assign, grant, convey or license, any rights in the invention to any person who could not be classified as an independent inventor under 37 CFR §1.27(a)(1) if that person had made the invention, or to any concern which would not qualify as a small business concern under 37 CFR §1.27(a)(2) or a nonprofit organization under 37 CFR §1.27(a)(3).

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[ ] persons, concerns, or organizations listed below

FULL NAME: KEY TECHNOLOGIES, Inc.
ADDRESS: 40 East Cross Street
Baltimore, Maryland 21230

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Reg. No. 34,145

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